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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,001	05/30/2001	Mitsuharu Ono	ASAHI-I-PC-1	4787
466	7590	05/11/2004	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

101,001

Applicant(s)

ONO et al

Examiner

SAUNDERS

Group Art Unit

1044

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/20/04
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed in** accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-34 is/are pending in the application.
- Of the above claim(s) 1, 5-10, 14-28 is/are withdrawn from consideration.
- ☐ Claim(s) 3-4, 31-34 is/are allowed.
- ☒ Claim(s) 2, 11-13 is/are rejected.
- ☒ Claim(s) 29-30 is/are objected to.
- ☒ Claim(s) 1-34 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Amendment of 2/20/04 has been entered. This has introduced no new matter.

The claims pending are 1-34.

Claims 2-4, 11-13 and 29-34 are examined.

The disclosure is objected to because of the following informalities: in the replacement paragraph beginning at page 24, line 4, in the penultimate line thereof, applicant is required to identify the residue numbers, of SEQ ID NO: 9 of which the recited sequence is a "piece". See MPEP 2424.03.

Appropriate correction is required.

Applicant's amendment has overcome previously stated 112 rejections of claims 2-4 and 29-34.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-13 were previously rejected for being incomplete (action of 3/5/03 at page 3). While applicant's amendment has entered certain of the steps suggested by the examiner, the claims remain incomplete in their embodiment of "detecting." Nothing is done after the "obtaining" step that would serve to detect the CD4+ cells.

In claims 12 and 13, second paragraph of each "said water-insoluble carrier" lacks antecedent basis.

Applicant's amendment and urgings have overcome prior art rejections of record.

New grounds of prior art rejection are stated infra.

Claims 2 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kazanori et al (unex JP 6-269663).

This reference has been noted by applicant at specification page 4.

Kazanori et al teach that it is of interest to remove CD4+ T-cells from patients who have various conditions involving undesired immune responses—e.g. delayed type hypersensitivities and autoimmune diseases; see para [0006] of translation. Kazanori et al accomplish such removal by providing an extracorporeal device in which a CD4 binding peptide is bound to a non-woven fabric, as a solid-phase.

The non-woven fabrics are considered as inherently having fibers and are thus consistent with instant claim language reciting “water-insoluble carrier in the form of a “fiber.” See claim 1 and translation paragraphs [0044], [0052] and [0057] referring to “fiber diameters.” Thus the carriers of the reference and of the instant claims are the same.

As to the peptides that bind CD4 disclosed by Kazanori et al, it appears that they contemplate and exemplify peptides of such a length that these would only correspond to one hypervariable(HV) region of the H or L-chain of an anti-CD4 antibody. See para [0015], [0040], [0049], [0051], [0055] and [0059]. However the reference also must be considered for what it discloses in the broadest sense; claim 2 (see translation page 4) recites that the peptide can be constituted of “at least 1 of the areas which are forming the complementary determination area.” The examiner interprets this to mean that more than one HV region can form the peptide, but that all must be from either the L or the H chain, since claim 1 of Kazanori et al recites “the amino acid sequence which

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constitutes the variable region of the light or heavy chain.” The examiner also notes that claim 1, unlike claim 2, does not recite an upper limit upon the length of the peptide. Examiner thus takes claim 1 of Kazanori et al as encompassing all of the V-region of either the L or H-chain.

According to the instant disclosure the instant invention can employ a “peptide of the H-chain only or peptide of the L-chain only” (page 40, second full para). The examiner thus sees what Kazanori et al encompass, in their longest embodied peptide (v-region of L or H-chain) as overlapping what applicant has disclosed instantly as more “minimal” antibody (L or H chain only). In any event, even if the examiner is incorrect in interpreting the instant specification, it is deemed that Kazanori et al’s teaching of the v-region of the L or H chain constitutes a teaching of a “single-chain antibody,” assuming the broadest reasonable definition thereof. Applicant’s disclosure is of excessive length for the examiner to find all of the other possible interpretations of what applicant might contemplate as an antibody of the instant invention. To distinguish from the single chain antibody of Kazanori et al, it is suggested that applicant’s claims recite the single chain antibody as “comprising an H chain fragment and L chain fragment bound in series”; see instant page 20.

Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kazanori et al in view of Huston et al (5,258,498).

Kazanori et al have been cited supra. Should applicant consider that their teachings do not encompass a single chain antibody, the examiner will rely upon the secondary teachings of Huston et al.

As noted supra Kazanori et al teach cell separation devices and methods in which a CD4 binding peptide is bound to a carrier in the form of a fiber. The examiner has noted that Kazanori et al exemplify short peptides representing HV segments of an antibody and that, at the most, they teach that one would employ an antibody representing the v-region of H or L-chain only.

Huston et al teach the basic concept of providing single chain antibodies which comprise all 6 HV regions from the v-region of an antibody, in the form of a single polypeptide which is correctly folded into a configuration that mimicks the natural Fv domain of the antibody. They clearly teach that the 3 HV (CDR) regions of each of the H and L-chains are "collectively responsible for antigen recognition and binding" (col.7, lines 23+); likewise they teach that the 3 HV (CDR) regions of each of the H and L chain "define an antigen binding site of the VH-VL dimer" forming the Fv, see col. 9, lines 28+. They also teach the 3 CDRs, from one of the chains forming an Fv, bind antigen but with a lower affinity than that of a full Fv; see col. 9, lines 43+.

Therefore, whether one considers Kazanori et al as teaching peptides that constitute only one HV (CDR) region or as constituting an entire V-region of a L or H-chain, one would have been motivated by Huston et al to provide, in lieu of such peptides, a single chain polypeptide that has all 6 HV, of both the L and H chains of an anti-CD4 antibody. Motivation would have been to increase the affinity of the CD4 binding capacity of the devices of Kazanori et al, since anyone of minimal acquaintance with the art would have recognized that a better affinity would permit better retention of CD4+ cells on the device and thus a cleaner separation of such cells from the fluid to be

returned to the patient. Claims 2 and 11 would thus have been obvious for the single chain embodiment.

Claims 2 and 11 would also have been obvious for the "chimeric" embodiment, since Huston et al teaches production of chimeric single chain antibodies that "minimize human immune reactions" (col. 7, lines 53+). One would have been motivated to thus "minimize human immune reactions" (i.e. reduce immunogenicity) because Kazanori et al motivate reduction of "adverse reactions" see para.[0061].

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 1, 5-10 and 14-28 are drawn to an invention nonelected with traverse in Paper No. 12 (filed 11/13/02). A complete reply to the final

rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

May 4, 2004


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~/1644